

No. COX 00-029
May 01, 2000

**Bulletin for VIOXX®:
New Obstacle Response**

TO:

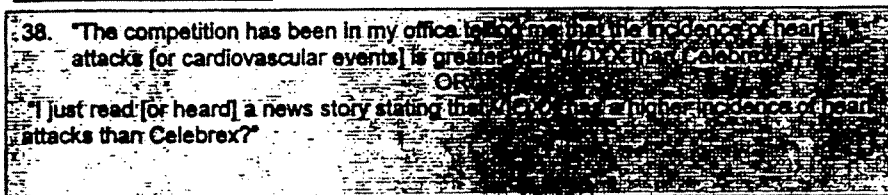
All field personnel with responsibility for VIOXX®

Action Required

PURPOSE:

To provide you with a new obstacle response relating to the press release and Searle/Pfizer's promotion that VIOXX has an increased incidence of heart attacks compared to Celebrex, based on the VIOXX GI Outcomes Trial compared to Celebrex in the CLASS trial.

Obstacle Response #38:



"Doctor, there are no head-to-head studies comparing the cardiovascular profile of the two drugs. As a result, you cannot compare the drugs and conclude that one drug had fewer events than the other. What you may be referring to is press reports of the incidence rates in two separate studies. In the VIOXX GI Outcomes Trial (VIGOR), the incidence of MI was 0.5% with VIOXX and 0.1% with naproxen. In a separate GI outcomes trial of Celebrex, the CLASS study, Searle has reported that the incidence of MI was 0.5% with Celebrex, 0.3% with diclofenac, and 0.5% with ibuprofen. Again, doctor, I want to emphasize that the results of two different studies can't be compared, and that's particularly true here when you have studies of differing duration and in different patient populations."

If needed, continue to address the physicians concerns with the cardiovascular effects of VIOXX by guiding them through the Cardiovascular Card as outlined in Roadmap for the CV Card.

Return to the appropriate HI NSAID or HI COXIB Top 5 Messages for VIOXX.

NOTE: There will be an additional PIR to address these issues available shortly.

If the doctor asks you further for the incidence of MI from the OA studies presented in the package insert for VIOXX tell them:

"In the clinical OA trials for VIOXX reported in our package insert, the incidence of MI was less than 0.1% with VIOXX."

If needed, continue to address the physician's concerns with the cardiovascular effects of VIOXX by guiding them through the Cardiovascular Card as outlined in Roadmap for the CV Card.

Return to the appropriate HI NSAID or HI COXIB Top 5 Messages for VIOXX.

Remember to provide appropriate balancing information as part of all product discussions.

ACTION REQUIRED:

1. Review and practice this obstacle response and use it in appropriate discussions on VIOXX® with your physicians:
2. Print the response provided, and add it to your Obstacle Response Guide. As with all other Obstacle Responses, the Response itself should not be shown to or left with physicians.

NOTE: All responses are available under the Obstacle Response Guide on the website for VIOXX® on the FSNet.

Remember to provide appropriate balancing information as part of all product discussions.

IF YOU HAVE ANY QUESTIONS CONCERNING THIS BULLETIN, PLEASE CONTACT THE MERCK NATIONAL SERVICE CENTER AT 1-800-NSC-MERCK.